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Edesa Biotech, Inc. (EDSA-NASDAQ)

EDSA: Set to Initiate Clinical Trial of EB05 in COVID-19 Patients…

Based on our probability adjusted DCF model that takes into account potential future revenues of EB01 and EB02, EDSA is valued at $10.00/share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based on future clinical results.

Current Price (08/21/20)	$6.89
Valuation	**$10.00**

OUTLOOK

On August 12, 2020, Edesa Biotech, Inc. (EDSA) announced financial results for the third quarter of fiscal year 2020 and provided a business update. The company recently received regulatory approval from Health Canada to begin a Phase 2/3 clinical trial of EB05 as a potential treatment for hospitalized COVID-19 patients. In July 2020, the company filed an IND with the U.S. FDA to expand the planned clinical trial of EB05 to include U.S. hospitals. We anticipate the trial getting underway, subject to funding and IND approval, in the next couple of months.

Edesa is also currently conducting a Phase 2b clinical trial of EB01, an $sPLA_2$ inhibitor, for the topical treatment of chronic allergic contact dermatitis. The dosing of patients is continuing and protocol amendments have been enacted to facilitate patient recruitment at most of the clinical sites.

SUMMARY DATA

52-Week High	**$9.45**
52-Week Low	**$1.64**
One-Year Return (%)	**70.54**
Beta	**0.42**
Average Daily Volume (sh)	**2,678,684**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**61**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**-10.1**
P/E using 2020 Estimate	**-5.9**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2019	0.1 A	0.1 A	0.1 A	0.1 A	0.4 A
2020	0.1 A	0.1 A	0.1 A	0.1 E	0.4 E
2021					0.4 E
2022					0.4 E

Earnings per Share

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2019	-$0.26 A	-$0.31 A	-$0.30 A	-$0.15 A	-$0.55 A
2020	-$0.15 A	-$0.17 A	-$0.19 A	-$0.18 E	-$0.70 E
2021					-$0.67 E
2022					-$0.62 E

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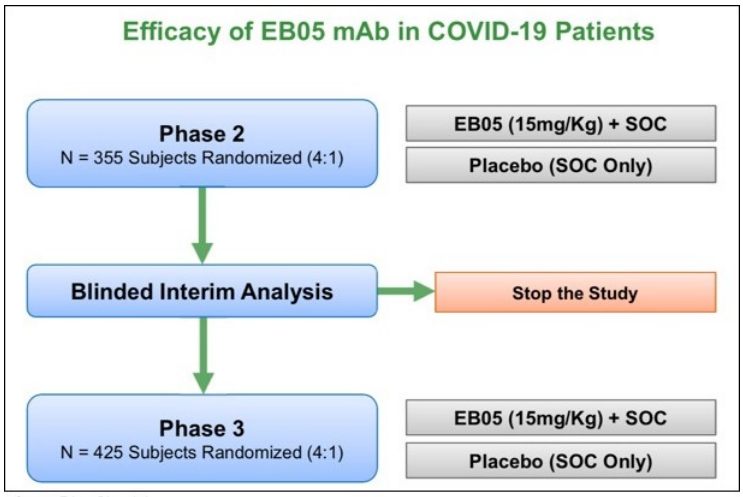
WHAT'S NEW

Business Update

Clinical Trial of EB05 Set to Initiate

In April 2020, Edesa announced an exclusive licensing agreement with Light Chain Bioscience for two clinical-stage monoclonal antibody assets targeting toll-like receptor 4 (TLR4) and C-X-C motif chemokine 10 (CXCL10). Light Chain received Series A-1 Convertible Preferred Shares at a value of $2.5 million with a fixed conversion price, up to $6.0 million for drug product inventory and other milestone fees, and the potential to receive up to $363.5 million in aggregate development, approval, and commercial milestone payments. Light Chain will also be eligible to receive royalties based on sales. Edesa will be responsible for development, product registration, and commercialization.

On June 15, 2020, Edesa announced that it received expedited approval from Health Canada to being a Phase 2/3 clinical trial of EB05 in patients with moderate to severe COVID-19. The company is planning to conduct a Phase 2/3 adaptive, multicenter, randomized, double blind, placebo controlled study to evaluate the safety and efficacy of EB05 in adult hospitalized patients with moderate to severe COVID-19 that can eventually progress to acute lung injury (ALI) and acute respiratory distress syndrome (ARDS), both of which are life threatening and require intensive medical care. A total of 355 patients are expected to be enrolled in the first phase of the trial. Patients will receive a single dose of either EB05 (15 mg/kg) + standard of care (SOC) or SOC only. If the results look promising the protocol allows for continuation of enrollment as a pivotal Phase 3 trial. An overview of the trial is provided below.



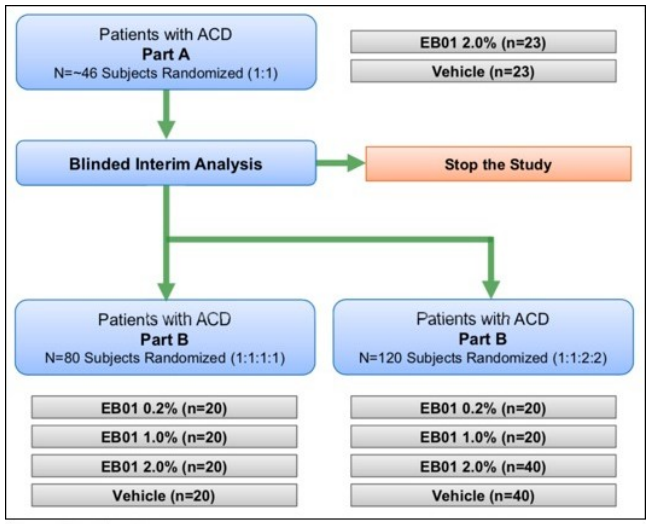
Source: Edesa Biotech, Inc.

On July 30, 2020, Edesa announced the filing of an Investigational New Drug (IND) application with the U.S. FDA for the initiation of a Phase 2/3 clinical trial of EB05 in hospitalized patients. Clearance of the IND will allow clinical sites at U.S. hospitals to be part of the upcoming Phase 2/3 trial. The company is currently pursuing government grants to accelerate site selection and to initiate patient enrollment.

Update on Phase 2b Trial of EB01

Edesa Biotech, Inc. (EDSA) is currently conducting a Phase 2b clinical trial of EB01 2.0% cream in patients with ACD. The randomized, double blind, placebo controlled, sample size adaptive design trial is expected to enroll approximately 46 patients in Part A randomized 1:1 between EB01 and placebo for 28 days of treatment. Following the enrollment of the first cohort, a blinded interim analysis will be conducted that can have the following outcomes: 1) stop the study for futility; 2) continue to the dose ranging portion of the trial with 80 additional subjects; or 3) continue to the dose ranging portion of the trial with 120 additional subjects.

The primary endpoint of the trial will measure the mean percent change from baseline in CDSI at Day 29, with secondary endpoints examining symptom reduction, dose-response relationships, and safety. An outline of the trial is shown below.



Source: Edesa Biotech, Inc.

In April 2020, the company filed a protocol amendment with the FDA for the ongoing Phase 2b trial. The amendment was filed such that changes to the study protocol could be made to mitigate the impact of the ongoing coronavirus pandemic. Included in the amendment were allowances for a reduction in the number of in-person office visits, remote telehealth appointments, and other procedural updates to simplify enrollment and patient care. While it is unclear exactly what impact the coronavirus epidemic will have on the timeline for completing the trial, we anticipate that there will be some delay in the interim readout.

Financial Update

On August 12, 2020, Edesa announced financial results for the third quarter of fiscal year 2020 that ended June 30, 2020. The company reported revenues of $0.11 million, which was derived from the sale of product inventory obtained in the reverse merger in June 2019. The cost of sales and services was $0.01 million for the third quarter of fiscal year 2020, due to the sales of product inventory obtained in the reverse merger acquisition. R&D expenses in the three months ending June 30, 2020 were $1.1 million, compared to $0.5 million for the same period last year. The increase was primarily due to increased expenses associated with the clinical trial of EB01 along with increased expenses related to the planned Phase 2/3 clinical trial of EB05. G&A expenses totaled $0.7 million in the third quarter of fiscal year 2020 compared to $0.8 million for the same period of 2019. The decrease was primarily due to decreased legal expenses partially offset by higher salary and personnel expenses.

As of June 30, 2020, Edesa had approximately $5.6 million in cash and cash equivalents. Subsequent to the end of the quarter, Edesa raised approximately $2.4 million from the exercise of warrants. We estimate that the company has sufficient capital to fund operations for at least the next 12 months. As of August 10, 2020, Edesa had approximately 9.4 million shares outstanding and when factoring in the Series A-1 convertible preferred, stock options, and warrants a fully diluted share count of approximately 12.4 million.

Conclusion

We are looking forward to the initiation of the Phase 2/3 clinical trial of EB05 for the treatment of moderate to severe COVID-19 patients and expect the trial to get underway prior to a potential increase in cases in the upcoming fall/winter timeframe. In addition, we hope to get an update on the timing of the interim efficacy analysis for the Phase 2b trial of EB01 once the impact of the pandemic is more fully known. With no changes to our model our valuation remains at $10.00.

PROJECTED FINANCIALS

Edesa Biotech, Inc.	FY2019 A	Q1FY20 A	Q2FY20 A	Q3FY20 A	Q4FY20 E	FY2020 E	FY2021 E	FY2022 E
EB01	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
EB02	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Total Revenues	**$0.4**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.4**	**$0.4**	**$0.4**
Cost of Sales	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	*75%*	-	-	-	-	-	-	-
Research & Development	$1.1	$0.5	$0.5	$1.1	$1.0	$3.2	$5.0	$6.0
General & Administrative	$2.0	$0.7	$1.1	$0.7	$0.8	$3.3	$3.2	$3.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($2.8)	($1.1)	($1.5)	($1.8)	($1.7)	($6.1)	($7.8)	($9.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	($0.0)	$0.1	($0.1)	($0.1)	($0.2)	($0.2)
Pre-Tax Income	($2.8)	($1.1)	($1.5)	($1.7)	($1.8)	($6.1)	($8.0)	($9.3)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($2.8)**	**($1.1)**	**($1.5)**	**($1.7)**	**($1.8)**	**($6.1)**	**($8.0)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.55)**	**($0.15)**	**($0.17)**	**($0.19)**	**($0.18)**	**($0.70)**	**($0.67)**	**($0.62)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	5.0	7.5	8.7	8.9	10.0	8.8	12.0	15.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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Source: Zacks Small Cap Research

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